



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEW
EPA SERIES 361

059102

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Chlorpyrifos-methyl
TOX Chem. No. 179-AA

TO: Jay Ellenberger
Insecticide Branch/RD (TS-769)

THRU: Robert B. Jaeger, Section Head
Review Section #1
Toxicology Branch/HED (TS-769)

FROM: Ray Landolt
Review Section #1
Toxicology Branch/HED (TS-769)

Registrant: Dow Chemical Co. letter of April 11, 1985.

Pesticide Petition: OF2423/OH5277 on stored grains.

Action Requested:

Withdrawal of the proposed tolerances on corn and request for a reevaluation of the impact of tolerance on the ADI by the Tolerance Assessment System (TAS).

Recommendation:

Tolerances on stored grains were established earlier this year when the use on such grains was conditionally registered pursuant to publication in the 40 CFR, June 27, 1985. The dietary contribution from these uses exceeded the ADI and therefore an evaluation of those tolerances was performed to determine which uses contributed the most to the TMRC.

The Toxicology Branch has calculated the impact of these tolerances on the ADI by the traditional "TMRC" system and the "new" Tolerance Assessment System (TAS). Presently there is no OPP or EPA policy concerning the preferential use of either system for estimating theoretical dietary exposure. Both of these systems are valuable tools for estimating the "theoretical" dietary exposure to residues from the proposed use. The results of these evaluations indicate a lower "theoretical" dietary

exposure determined by the TAS. Although it must be emphasized that neither system considers the actual dietary exposure to the residue(s) likely to occur, the TAS probably gives a better estimate of dietary consumption for the various food commodities. Therefore, for the record, Toxicology Branch (TB) would like to clarify it's position relevant to establishment of these grain tolerances. TB concurrence with the proposed Federal Register notice for PP#OF2423 is conditional until November 1, 1985 pending review of the mutagenicity studies submitted by Dow Chemical Co. (letter of June 25, 1985). The Federal Register notice gave considerable weight to the TAS estimates in determining the residue likely occur from these uses. However, TB believes the emphasis on the TAS as a more reasonable determination of actual dietary consumption of residues is overstated. To clarify the issue, TB recommends additional residue data be obtained from this authorized use on grain in order to better estimate the "actual" dietary exposure.

Total diet surveys conducted by FDA as well as analysis of individual table-ready products indicate that chlorpyrifos, a similar pesticide to chlorpyrifos-methyl, demonstrated little, if any, residues resulting from uses on grains through 1979 (average concentration was 0.0006 ppm resulting in an average intake of 0.264 ug/day). TB believes these data are more relevant to the grain tolerances than the theoretical calculations currently used. These surveys estimate little impact upon the ADI via determinations of "actual" residues. Toxicology Branch recommends that actual residues for chlorpyrifos-methyl be determined for all presently registered uses and that any additional tolerances be withheld pending the determination of such residues likely to result from any additional uses(s).

Unverified Printout

ACCEPTABLE DAILY INTAKE DATA

DRAFT

Dog	NOEL	S.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day (60kg)
0.100	4.00	10	0.0100	0.6000

Current Action 0F2423

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Barley(8)	6.000	0.03	0.00270
Oats(102)	6.000	0.36	0.03219
Rice(137)	6.000	0.55	0.04967
Sorghum(147)	6.000	0.03	0.00270
Wheat(170)	6.000	10.36	0.93265
Cattle(26)	1.000	7.18	0.10777
Goats(62)	1.000	0.03	0.00045
Sheep(145)	1.000	0.19	0.00291
Hogs(69)	0.500	3.43	0.02575
Horses(208)	0.500	0.03	0.00023
Milk&Dairy Products(93)	0.020	28.62	0.00858
Eggs(54)	0.050	2.77	0.00208
Poultry(128)	0.100	2.94	0.00441

MPI	THRC	% ADI
0.6000 mg/day(60kg)	1.1721 mg/day(1.5kg)	195.35

ssr/12-3-82

Request Form For ADI Printout

179AA

Common name:

Chlorpyrifos-methyl

CFR Number:

180.508

Petition Number(s):

0F2423 / 045277

Copy of Section F attached: Yes/No

Commodity & requested tolerance level:

Withdraw the proposed tolerance for
corn, grain from the ADI request of 8-19-83

Was previous "Current Action" TOX approved or not?

No

Are the "Published Tolerances" current? Yes/No

(Please call: Rick Talento
x 382-3631 (FR Section).)

Any further update, NOEL, etc that I should know?

Reviewer:

Ray Lambert

Date:

May 6, 1985



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Chemical: Chlorpyrifos-methyl (ANSI)

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